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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,749	07/22/2003	Oystein Fodstad	8966.31USRE	1257

7590 03/31/2005

Abbott Laboratories, Inc. Pharmaceuticals
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EXAMINER	
GABEL, GAILENE	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,749	FODSTAD ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20,25-59 and 61-91* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20,25-59 and 61-91* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/704,619.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/22/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendment

1. Applicant's preliminary amendment filed on 7/22/03 of US Patent Number 6,265,229, filed as a Reissue Application on 7/24/01, is acknowledged. Claims 11, 21-24, and 60 have been cancelled. Claims 1, 3, 43, 45, 50, 74, and 86 have been amended. Claims 89-91 have been added. Accordingly, claims 1-10, 12-20, 25-59, and 61-91 are pending in this reissue application.

2. It is noted that ASN 10/359,677 filed 2/10/03 is a reissue application for US Patent 6,184,043 having common inventors and assignee with the instant reissue application. However, the claims as currently recited in each reissue application, are not related because they claim priority to different applications and are both drawn to patentably distinct inventions.

Amendment Non-compliance

3. The amendment filed on 7/22/03 proposes amendments to claims that do not comply with 37 CFR 1.173(b), which sets forth the manner of making amendments in reissue applications. The requirements of 37 CFR 1.173(b)(2) and (d), states: all subject matter being added to a patent or to a new claim requires rewriting and underlining of the entire new claim. In this case, new claims 89-91 have not been

presented in the marked up copy of the claims as underlined. A supplemental paper correctly amending the reissue application is required.

Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b).

Oath/Declaration

4. The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following: page 4, item number 9 of the oath/declaration fails to state that "every or all errors being corrected in the reissue application up to the filing of the oath or declaration arose without any deceptive intention on the part of the applicant". Correction is required.

In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

5. In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

Claims 1-10, 12-20, 25-59, and 61-91 are rejected as being based upon a defective reissue oath/declaration under 35 U.S.C. 251. See 37 CFR 1.175. The nature of the defect is set forth above.

Receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) will overcome this rejection under 35 U.S.C. 251. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

> "Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant."

6. Claims 1-10, 12-20, 25-59, and 61-91 are rejected as being based upon a defective reissue oath/declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) in the oath/declaration is set forth in the discussion above in this Office action.

Recaptured Subject Matter

7. Claims 1-10, 12-20, 25-59, and 61-91 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Pannu v. Storz Instruments Inc.*, 258 F.3d 1366, 59 USPQ2d 1597 (Fed. Cir. 2001); *Hester Industries, Inc.* v. *Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement,* 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp.* v. *United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that applicant previously surrendered in the prosecution of the

application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

There are three steps in determining the presence of recapture in a reissue application: 1) to determine whether and in what aspects the reissue claims are broader than the patent claims, 2) to determine whether the broader aspects of the reissued claims relate to surrendered subject matter, and 3) to determine whether the reissued claims were materially narrowed in other respects to avoid the recapture.

In this case, independent claims 1, 43, and 86 were amended to delete the recitation of "which filter provides a matrix for cell growth;" and "growing cells of the separated particle-target cell complexes on the filter", and the deletion of such recitation broadens the scope of the claimed invention. The removal of the recitation of "which filter provides a matrix for cell growth; growing cells of the separated particle-target cell complexes on the filter" appears to be subject matter encompassed within the meaning of a broadened aspect of the reissue which, under 35 U.S.C. 251, is an improper recapture of broadened claimed subject matter surrendered during the prosecution of the application for the patent, because such limitations were agreeably set forth to render the claims allowable.

Referring back to Applicant's amendment (B) filed 2/28/1996 in the prosecution of US Patent 6,265,229, at page 21, last two paragraphs, Applicant argued that Funderud et al. as prior art, "is a coarse separation of cells" ... which "uses [further] low

pH". To this end, Applicant stated that, "low pH would in the present method destroy the cells and lead to that they cannot be grown in culture". Also referring back to Applicant's amendment (D) filed 3/26/1999 in the prosecution of US Patent 6,265,229, at page 16, last six lines of the second full paragraph, Applicant deliberately argued that, "the cells of the present invention cannot be pretreated since they are alive under the present method and can be cultured after they have been connected to the particles." The claimed methods and kit of US Patent 6,265,229, therefore, require for cells to remain live and viable for purpose of proliferation in culture using a cell growth matrix, and require use of mild detergents to remove non-specific binding and avoidance of strong detergents and deterrent factors (taught by prior art) that affect the viability of live cells. In both instances argued by Applicant, the inclusion of a filter having a matrix capable of both cell growth and separation of particle-target cell complexes on the filter are required limitations in the claims that obviated prior art and that rendered the claims allowable. To reiterate, the claims in US Patent 6,265,229 were allowed for reasons that "the prior art of record does not teach or fairly suggest a method and kit therefor, which combines immunoparamagnetic selection of a subpopulation of cells from a cell suspension population followed by filter separation / concentration using a device having a filter with pore size and shape capable of retaining particle-cell complexes or rosettes and which filter provides a matrix for cell growth". Additionally, claims 18, 25, 40, and 86 appear to maintain limitations encompassing cell cultures requiring "a filter that provides a matrix for cell growth". For at least all these reasons, it appears that the broadening aspect (in the reissue) relates

to subject matter encompassing 1) use of a filter that provides a matrix for cell growth, and 2) growing cells of the separated particle-target cell complexes on the filter, which were previously surrendered in the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

In as far as new claims 89-91, claim 89 entirely omits the limitations recited supra, which were both added and argued during the original prosecution of US Patent 6,265,229 in order to overcome art rejection. Such an omission, even if it includes other limitations making the reissue claim narrower than the patent claim in other aspects, is impermissible recapture because it appears to narrow the claim in other respects to avoid the recapture.

In as far as the preliminary amendment, Applicant also failed to set forth reasons or arguments as to why the limitations deleted from the reissue claims should be removed, how all the errors made in the claims occurred, and why the patent is partially inoperative, as a result of effecting such limitations in the claims.

8. The reissue oath/declaration filed with this application is, therefore, defective because the error which is relied upon to support the reissue application is not an error upon which a reissue can be based. See 37 CFR 1.175(a)(1) and MPEP § 1414.

Claims 1-10, 12-20, 25-59, and 61-91 are rejected as being based upon a defective oath/declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defects in the oath/declaration, is set forth in the discussion above in this Office action.

Information Disclosure Statement

9. It is noted that an IDS with listing of all references cited in the front of US Patent Number 6,265,229 has not been provided in this reissue application. 37 CFR 1.98(b) requires an IDS with a list of all patents, publications, or other information be submitted for consideration by the Office.

10. Claims 1-10, 12-20, 25-59, and 61-91 are free of the prior art. The prior art does not teach or fairly suggest a method and kit therefor, for detecting specific target cells in a cell suspension wherein labeled antibody / target cell / particle-immobilized antibody complexes are separated from unbound components or unspecifically bound components by immunoparamagnetic selection of the target cells from the cell suspension population, followed by filter separation / filtration / concentration of the cells using a filter with intermediate pore size (20 um as defined in the specification) capable of retaining particle-target cell rosettes or complexes, to thus allow subsequent detection and quantitation of the complexes.

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene T. Gabel
Patent Examiner
Art Unit 1641
March 18, 2005
23

Jean F. Vollano

JEAN F. VOLLANO
PRIMARY EXAMINER